

In the Office Action, the Examiner has acknowledged Applicants' claim for foreign priority based on the following applications filed in Australia: PN 6135 filed on October 23, 1995, PN 7276 filed December 22, 1995, and PO 33.9 filed on September 9, 1996. The Examiner points out that certified copies of these Australian applications have not been filed as required by 35 U.S.C. §119(b).

Applicants submit that certified copies of the above Australian applications will be timely filed.

The specification is objected to for the following reasons. The Examiner points out that the Brief Description of the Drawings only refer to Figure 1, whereas Figure 1 is shown in two panels (Figure 1A and Figure 1B). The Examiner also points out that the description for the figures, found under the title "In the Figures", should follow the title "Brief Description of the Figures" and should be placed between the Summary Of The Invention and the Detailed Description Of The Invention. The Examiner also suggests that the preferred layout for patent applications be used.

In response, Applicants have amended the specification in accordance with the Examiner's recommendations. Specifically, the description of Figure 1 at page 26 of the specification has been amended to refer to Figure 1A and Figure 1B. The title "In the Figures", has been replaced with "BRIEF DESCRIPTION OF THE DRAWINGS". The headings "FIELD OF THE INVENTION", "BACKGROUND OF THE INVENTION" and "DETAILED DESCRIPTION OF THE INVENTION" have also been inserted into the specification at the appropriate locations. Accordingly, Applicants respectfully request the withdrawal of the objection to the specification.

In the Office Action, claim 30 is rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabled. Claim 30 is further rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite for reciting "substantially". Claim 30 is also rejected under 35 U.S.C. §102(b)

as allegedly anticipated by Marra et al., and by Yokota et al. (EP 138133-A, 1985), respectively. Furthermore, claim 30 is rejected under 35 U.S.C. §§101/112 as not supported by either a specific and substantial asserted utility or a well-established utility.

In this regard, Applicants respectfully disagree with the Examiner. However, in an effort to advance the prosecution of the present application, claim 30 has been canceled without prejudice by way of the instant amendment. Applicants reserve the right to file one or more continuing applications directed to the subject matter of claim 30.

Claims 20-27 are rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabled. The Examiner contends that the specification, while enabling for isolated haemopoietin receptors with the amino acid sequences set forth in SEQ ID NOs: 13, 15, 17, 19, 25 or 29, comprising the amino acid motif set forth in SEQ ID NO: 1 (TrpSerXaaTrpSer), it is not enabling for “all” isolated haemopoietin receptors comprising SEQ ID NO: 1, or “all” isolated haemopoietin receptors comprising SEQ ID NO: 1 wherein Xaa is Asp or Glu, or isolated haemopoietin receptors comprising amino acid sequences “substantially” as set forth in SEQ ID NOs: 13, 15, 17, 19, 25 or 29.

In this regard, Applicants respectfully disagree with the Examiner. However, in an effort to advance the prosecution of the present application, Applicants have amended claims 20-27. More specifically, claim 20 has been amended to recite amino acid sequences (i) that share at least about 90% similarity to the specifically exemplified polypeptides, or (ii) that are encoded by nucleotide sequences that share at least about 85% identity with the specifically exemplified polynucleotides, or (iii) that are encoded by nucleotide sequences which hybridize under high stringency conditions to the specifically exemplified polynucleotides. Support for such amendment is found throughout the specification, e.g., at page 9, lines 9-11 for “at least about 90-95%”

similarity with respect to amino acid sequences; at page 8, lines 1-3 for “at least about 80%” or “at least about 90%” similarity with respect to nucleotide sequences; and at page 6, lines 23-26 for the term “high stringency conditions”. Claims 22-27 have been amended to delete the phrase “substantially as”.

Applicants respectfully submit that claims 20-27 as amended are fully supported by the present specification. The specification teaches the isolation of receptor-encoding cDNA and genomic DNA clones by using oligonucleotides designed against the conserved TrpSerXaaTrpSer (SEQ ID NO: 1) motif. See, e.g., pages 33-34 and 38. The specification also teaches how to isolate clones bearing sequence similarities to a receptor-encoding cDNA by using fragments of such cDNA in hybridization procedures. See, e.g., pages 34-35 (describing the isolation of NR clones from murine brain cDNA library using fragments of NR clones isolated from murine testis cDNA library), and pages 36-37 (describing the isolation of multiple human NR cDNA clones by using fragments of a murine NR cDNA). In addition, the specification teaches how to express and purify the receptor proteins encoded by the isolated cDNA molecules. See, e.g., pages 45-55. Moreover, the specification teaches how to assess the sequence similarity between a newly cloned cDNA (and the encoded protein) and a member of the present receptor family. See, e.g., pages 39-41 and 58. In light the present teaching, those skilled in the art are fully enabled to make and use the isolated receptors as presently claimed. As such, the rejection of claims 20-27 under 35 U.S.C. §112, first paragraph, is overcome. Withdrawal of the rejection is respectfully requested.

Claims 20-27 are rejected under 35 U.S.C. §112, second paragraph, as allegedly indefinite. The Examiner contends that claim 20 is indefinite for the recitation “an isolated *novel* haemopoietin receptor.” The Examiner suggests that the term “novel” be deleted from the claim. The Examiner also contends that the term “substantially” in claims 22-27 is vague and indefinite.

In response, Applicants have deleted the term “novel” from claim 20 and the term “substantially” from claims 22-27. It is respectfully submitted that the rejection of claims 20-27 under 35 U.S.C. §112, second paragraph, is overcome. Withdrawal of the rejection is therefore requested.

Claim 20 is rejected under 35 U.S.C. § 102(b) as allegedly anticipated by D’andrea et al. (WO9008822, 1990).

It is observed that D’andrea et al. teach an erythropoietin receptor with 507 amino acid residues and the polynucleotide encoding said receptor. Amino acid residues 232 to 236 of the erythropoietin receptor disclosed by D’andrea comprise TrpSerAlaTrpSer. The Examiner contends that the instant claims to an isolated receptor which comprises the amino acid motif set forth in SEQ ID NO: 1 (TrpSerXaaTrpSer), wherein Xaa can be any amino acid, is anticipated by the D’andrea et al. reference.

Applicants respectfully submit that claim 20 as amended is drawn to an isolated receptor having at least about 90% similarity to the specific SEQ ID NOs recited therein, or is encoded by a nucleotide sequence having at least about 85% identity with the specific SEQ ID NOs recited therein, or is encoded by a nucleotide sequence which hybridizes under high stringency conditions to the specific SEQ ID NOs recited therein. The recited SEQ ID NOs presently claimed are not disclosed by the cited prior art reference. Applicants submit that amended claim 20 is not anticipated by the D’andrea et al. reference. Accordingly, the rejection of claim 20 under 35 U.S.C. § 102(b) is obviated and withdrawal thereof is respectfully requested.

Claims 20-24 are rejected under 35 U.S.C. §101 and §112. The Examiner alleges that the claimed invention is not supported by either a specific and substantial asserted utility or a well-

established utility as required under 35 U.S.C. §101, and therefore, those skilled in the art would not know how to use the claimed invention.

Specifically, the Examiner asserts that the specification does not disclose any functional activity of the claimed receptor, or any information as to which hemopoietin the claimed receptor binds to, or what biological process the claimed receptor is involved in. The Examiner acknowledges that the specification discloses that the claimed hemopoietin receptor is expressed specifically in certain tissues, and that lack of this receptor is lethal during embryonic development. However, the Examiner contends that the specification does not teach the significance of these observations. According to the Examiner, without knowing the specific cytokine that binds to the claimed receptor, the biological function of the claimed receptor, or the pathological conditions the claimed receptor is associated with, those skilled in the art would not know how to use the claimed receptor.

Applicants submit first that, contrary to the Examiner's allegation, the specification asserts specific and substantial utilities of the claimed receptor. In this regard, Applicants draw the Examiner's attention to page 32, lines 7-10 of the present specification, which discloses the utility of the claimed subject matter in the field of reproduction. This asserted utility is based on the results described in Example 15, which show that the lack of NR6 (the claimed receptor) is lethal during embryonic development or immediately after birth. Thus, as asserted at page 32, lines 8-10 of the instant specification, diagnostic assays are disclosed for testing individuals in order to obtain the information of the genetic composition of their NR6 genes. Apparently, two NR6<sup>+/-</sup> carriers could give rise to an offspring of NR6<sup>-/-</sup> with developmental problems. Similar diagnostic assays are disclosed using antibodies raised against the claimed receptor in order to determine the presence or absence of the receptor in expected tissues and organs in accordance with the characterization of

the present invention. Thus, the presently claimed receptor and the encoding genes clearly have specific and substantial utilities, at least in the field of genetic counseling, independent of the identification of the ligand or the precise biological process involved.

Applicants further submit that the utility of the claimed receptor is further supported by the recognition that the claimed receptor is a member of the hemopoietin receptor family. Based on the discoveries on the functional activities of other members of the hemopoietin receptor family such as IL-2, IL-3, IL-5, G-CSF, GM-CSF, EPO and many others, it is reasonable for those skilled in the art to expect, that the claimed receptor is involved in regulation of cell proliferation and differentiation. Thus, as asserted in the specification, the claimed receptor can be employed to make agonists or antagonists for modulating the expression of the claimed receptor in those disorders associated with abnormal cell proliferation and differentiation.

In view of the foregoing, it is respectfully submitted that the specification has asserted utilities that are credible to those skilled in the art. As such, the rejection of claims 20-24 under 35 U.S.C. §101 is overcome and withdrawal thereof is therefore requested.

It is further submitted that the present specification teaches those skilled in the art how to use the claimed receptor. Thus, the rejection of claims 20-24 under 35 U.S.C. §112 is overcome. Withdrawal of the rejection is respectfully requested.

Finally, Applicants submit that claims 35-46 have been added. Support for added claim 35 is found in the specification, e.g., at page 9, lines 9-11. Support for added claim 37 is found in at page 8, lines 1-3 of the specification. Support for added claim 35 is found in the specification, e.g., at page 6, lines 23-26.

Added claims 36, 38 and 40 depend from new claims 35, 37 and 39, respectively, and include the additional recitation that Xaa is Asp or Glu. Support for this amendment can be found in original claim 21 for example.

Added claim 41, depending from added claim 39, further delineates the high stringency conditions. Support for claim 41 can be found, for example, at page 6, lines 23-26 of the specification.

Added claim 42 depends from claim 41 and includes the additional recitation that the high stringency conditions comprise 0.1xSSC/0.1% (w/v) SDS at 65°C for 30 mins as washing conditions. Support for this recitation can be found, for example, at page 43, line 22.

Added claims 41-46 are independent claims drawn to the specific amino acid sequences, support for which appears throughout the specification.

It is respectfully submitted that claims 35-46 are fully supported by the specification. No new matter is introduced.

In view of the foregoing amendments and remarks, it is firmly believed that the subject application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,



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